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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/686,730 | 10/17/2003 | Moris Topaz | 030231-0151 | 8302 |
| 22428 | 7590 | 03/06/2006 | EXAMINER | |
| FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 | | | SCHUBERG, LAURA J | |
| ART UNIT | | PAPER NUMBER | | 1651 |

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|----------------------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/686,730 | TOPAZ, MORIS | |
| | Examiner Laura Schuberg | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/478,363.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/17/04.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/478,363, filed on 01/06/2000.

Claim Objections

Claims 14-16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Claim 11 is objected to because of the following informalities: The term "for" is misspelled. There is a period improperly placed in line 3 that should be a comma. Appropriate correction is required.

Claim 5 is objected to because of the following informalities: Claim 5 has a number 1 where the letter I should be in ml/min. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7, and 10-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 10, 13, 14-16 are drawn to a method for reducing and limiting cavitation in ultrasound assisted lipoplasty where the introduction of a gas into the irrigation solution is required.

The state of the art is represented by Carter (US 5,362,309). Carter describes a method for using an ultrasonic apparatus where the step of promoting cavitation includes the introduction of a seed fluid where the seed fluid includes an aqueous saline solution containing carbon dioxide (col 3 lines 24-28). Carter also teaches that the concentration of the carbon dioxide is not to exceed 10 grams weight per liter of fluid (col 6 line 6-8). This teaching is significant because it addresses the fact that if CO₂ concentrations in an aqueous solution are allowed to pass a certain level they cause a decrease in pH such as to make the solution so acidic as to be non-biocompatible. Carter discloses that as the liquid exits its container, its pressure drops to atmospheric pressure and the CO₂ begins to come out of the solution in the form of small gas bubbles (seed bubbles) (col 6 line 7-14). Since cavitation occurs when the magnitude of the vacuum portion of the pressure-vacuum cycle is sufficiently high that dissolved gases in the fluid come out of solution in the form of small observable bubbles, one can

ascertain that the introduction of CO₂ gas into the liquid used with ultrasound energy actually causes cavitation.

Claims 10 and 13 of Applicant's method adds gas to the irrigation solution and maintains that cavitation is limited and reduced, but does not include any additional steps to control or limit the introduction of the gas (CO₂) beyond what Carter has disclosed. This information is critical for one who would practice the claimed invention as described in light of the fact that Carter teaches that the introduction of CO₂ into the liquid causes cavitation.

In light of Applicant's disclosure (p.7) that the presence of carbon dioxide nearly eliminates sonoluminescence generated by the cavitation phenomenon, one of ordinary skill in the art would expect cavitation to be reduced whenever carbon dioxide is introduced into an irrigation solution in the presence of cavitation. Clearly this is not the case with respect to the disclosure of Carter.

Therefore, one of skill in the art, in order to practice the method of Applicant's claimed invention with a reasonable expectation of reducing and limiting cavitation would require additional information. In the absence of this information, the claimed invention fails to find support and for this reason claims 10,13 (and claims 14-16 as far as they are dependent upon claims 10 and 13) are not enabled.

Claims 5-7 are drawn to the method of claim 1 which is a method for using a biocompatible, injectable aqueous solution in high intensity ultrasound assisted surgery at greater than 10 W/cm² CW at 20-100 kHz with an amplitude of 60-320 μ , wherein the

solution comprises a gas selected from the group consisting of carbon dioxide, nitrogen or mixtures thereof and wherein the gas is passed through the solution at a flow rate of 10 to 500 ml/min, 50 to 200 ml/min, 100 ml/min.

Claim 11 is drawn to a method for removing target tissue from a patient comprising an irrigation solution, an ultrasonic probe and characterized in that a gas selected from the group consisting of carbon dioxide, nitrogen and mixtures thereof is introduced into the irrigation solution in the are exposed to high intensity ultrasound energy.

Claim 12 is drawn to a method for removing target fatty tissue from a patient comprising an irrigation solution, an ultrasonic probe and characterized in that a gas selected from the group consisting of carbon dioxide, nitrogen and mixtures thereof is introduced into the irrigation solution in the are exposed to high intensity ultrasound energy.

The state of the art is represented by Eguchi (Rinsho Ganka. Japanese Journal of Clinical Ophthalmology 1987). In the abstract, Eguchi describes a method of ultrasonic phacoemulsification surgery using different irrigating solutions. Eguchi concludes that solutions either containing bicarbonate equilibrated with CO₂ or dextran are not suitable for phacoemulsification because air bubble formation interferes with surgical manipulations in the anterior chamber. The reference teaches that solutions containing bicarbonate and glucose, but not equilibrated with CO₂ may be the choice for phacoemulsification. Since ultrasonic phacoemulsification is one of the types of surgery that uses high intensity ultrasound energy (HIUE) during the surgery, this

disclosure leads to a lack of predictability in the art as far as using an irrigation solution equilibrated with carbon dioxide is concerned.

While Applicant has illustrated the influence of various gases on sonoluminescence, chemi-sonoluminescence and the formation of free radicals generated by HIUE (figures 1-3), Applicant has not provided direction on how to avoid the air bubble formation that the prior art has indicated was a factor with using an irrigation solution equilibrated with carbon dioxide.

While Applicant's lack of a working embodiment of the claimed invention cannot be a sole factor in determining enablement, its absence, in light of the unpredictable nature of the art and the direction Applicant presents, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole.

Therefore, one of skill in the art in order to practice the method of Applicant's claimed invention with a reasonable expectation of success would require additional information. In the absence of this information, the claimed invention fails to find support and for this reason claims 11-16 are not enabled.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 provide for the method for use of a biocompatible injectable aqueous solution, but since the claims do not set forth any steps involved in the method, it is

unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Zocchi, M (Clinics in Plastic Surgery 1996).

Claim 1 is drawn to a method for using a biocompatible, injectable aqueous solution in high intensity ultrasound assisted surgery at greater than $10 \text{ W/cm}^2 \text{ CW}$ at 20-100 kHz with an amplitude of 60-320 μ , wherein the solution comprises a gas selected from the group consisting of carbon dioxide, nitrogen or mixtures thereof.

Claim 2 is drawn to the method of claim 1 wherein the gas is at a concentration which is higher than the concentration in a solution which is in equilibrium with air at 25°C and 98.1 Kp (1 atm) pressure.

Claim 3 is drawn to the method of claim 1 wherein the surgery is lipoplasty.

Claim 4 is drawn to the method of claim 1, wherein the gas is carbon dioxide.

Zocchi teaches a method for removing target fatty tissue from a patient using high intensity ultrasound energy assisted surgery at 20 kHz (p.577 col 2), at greater than 10 W/cm² CW and an amplitude level of 140 to 150 μ (p.579 col 1). Carbon dioxide, nitrogen and mixtures thereof are inherently present in the solution due to the transfer of gases upon exposure to air.

Zocchi teaches irrigating a treatment site with hypotonic solution (p.579 col 2), inserting a probe into the target, fatty tissue (p. 581 col 1), ultrasonically vibrating the probe at standard conditions (p.581 col 2) and thereby liquefying fat (p.575 col 1). Suction and removal of the target tissue is taught as well (p.585 col 1).

Zocchi also teaches the addition of sodium bicarbonate to the hypotonic solution (p.580 col.2). Upon dissolving in the hypotonic solution, this sodium bicarbonate would produce carbon dioxide at a concentration which is higher than the concentration in a solution which is in equilibrium with air at 25°C and 98.1 Kp (1 atm) pressure and thus meeting the claimed limitations.

Therefore, Zocchi inherently anticipates claims 1-4 of Applicant's claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1651

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zocchi, M (Clinics in Plastic Surgery 1996) in view of Richmond et al (US 5,328,701).

Claims 8-9 are drawn to the method of claim 1 wherein the solution further comprises a water soluble scavenger, vitamin C.

Zocchi teaches the method of claim 1 as described above and includes the gas, carbon dioxide.

Zocchi does not teach adding a water soluble scavenger to the solution, but does teach an aggressive anti-free-radical therapy based on high doses of vitamin C prior to the surgery (p. 579 col 1).

Richmond et al teach a tissue irrigation solution used in surgical procedures and suggest the addition of free radical scavengers such as ascorbic acid (vitamin C) (col 3 line 41-44).

One of ordinary skill in the art would have been motivated to include vitamin C in the irrigation solution of Zocchi since it would have put the vitamin C in direct contact with the free radicals produced by cavitation that Zocchi was trying to address with the pre-surgery oral dosages (p. 579). One of ordinary skill in the art would also have been motivated because Richmond et al teach that protection of tissues during surgery is of paramount importance and that surgical procedures cause damage to tissues and cells from the invasion of surgical instruments, tissue/tissue contact and the irrigation media (col 1 line 14-16). One of ordinary skill in the art would have had a reasonable expectation of success including vitamin C in the irrigation solution of Zocchi since Richmond et al was incorporating vitamin C in an irrigation solution used for surgical procedures and Zocchi's solution was also intended for a surgical procedure.

Conclusion

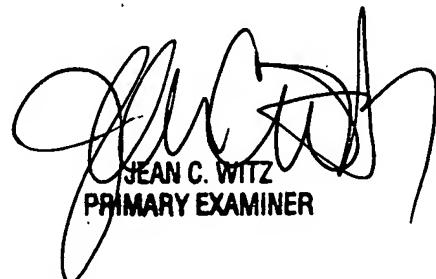
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura Schuberg



JEAN C. WITZ
PRIMARY EXAMINER